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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,949	09/05/2003	Peter Hilfenhaus	P24008	7944

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EXAMINER

MATZEK, MATTHEW D

ART UNIT PAPER NUMBER

1771

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/654,949	Applicant(s) HILFENHAUS ET AL.	
	Examiner Matthew D. Matzek	Art Unit 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-187, 189, 190 and 192-210 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-187, 189, 190, and 192-210 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The amendment dated 9/29/2006 has been fully considered and entered into the Record. Amended claims 105, 180, 189, 190, 192 and 193 contain no new matter. New claims 209 and 210 have been added. Claims 1-104, 188 and 191 have been canceled. Claims 105-187, 189, 190, and 192-210 are currently active. The previously applied prior art rejections have been withdrawn as the applied references failed to teach an outermost liquid permeable layer and a second layer arranged on the first layer, wherein a coating of an antimicrobial in elemental form as such is present between the first and second layers as amended.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 105-112, 119-123, 125-132, 139-141, 147-151, 163, 164, 167, 170, 174-185, 189, 192, 193, 197-199, 206, 207 and 209 are rejected under 35 U.S.C. 103(a) as obvious over Burrell et al. (US 2003/0054046).

a. Burrell et al. teach a treatment of inflammatory skin conditions with antimicrobial metals, most preferably silver, via a coating of antimicrobial metals (Abstract). One form of the anti-inflammatory article may be a wound dressing. The dressing is formed of a perforated material that allows for fluids to penetrate or diffuse through in either or both directions. The perforated material may be a woven, nonwoven, net or mesh or even open-cell foam. The perforated material may be made of cotton, polyethylene, nylon, polypropylene, polyester, elastomer, or polyurethane [0106].

b. If desired, a second absorbent layer is formed from an absorbent material for holding sufficient moisture next to the skin in order to activate the antimicrobial metal coating, that is to cause release of ions, molecules, atoms or clusters of the antimicrobial metal in order to cause an antimicrobial and anti-inflammatory effect. Preferably, the absorbent material is an absorbent needle punched non-woven rayon/polyester core such as SONTARA.TM. 8411, a 70/30 rayon/polyester blend. However, other suitable absorbent materials include woven or non-woven materials, non-woven being preferred made from fibers such as rayon, polyester, rayon/polyester, polyester/cotton, cotton and cellulosic fibers. Exemplary are creped cellulose wadding, an air felt of air laid pulp fibers, cotton, gauze, and other well known absorbent materials suitable for medical dressings [0108].

c. A third layer of the dressing, if used, is preferably formed of perforated, non-adherent material such as used in the first layer. This allows moisture penetration as sterile water and the like are added in order to activate the antimicrobial metal coating [0109]. Additional layers may be included between or above the first, second and third layers as is well known in medical dressings. The coated dressing layers may be combined with an adhesive layer, in a well-known manner [0110].

d. The dressing may be used as a single layer, or may be used as multiple layers laminated together at intermittent spaced locations across the dressing by ultrasonic welds. Ultrasonic welding is a known technique in the quilting art. Briefly, heat (generated ultrasonically) and pressure are applied to either side of the dressing at localized spots through an ultrasonic horn so as to cause flowing of at least one of the

plastic materials in the first and second layers and the subsequent bonding together of the layers on cooling. The welds appear at localized circular spots and are preferably less than 0.5 cm in diameter [0111].

e. The antimicrobial metal is deposited as a thin metallic film on one or more surfaces of the dressing [0120]. To form a three-layer dressing, two layers of this coated dressing material were placed above and below an absorbent core material formed from needle-punched rayon/polyester (SONTARATM 8411). With the silver coating on both the first and third layers, the dressing may be used with either the blue coating side (Al) or the silver side in the skin facing position. For indicator value, it might be preferable to have the blue coating visible. The three layers were laminated together by ultrasonic welding to produce welds between all three layers spaced at about 2.5 cm intervals across the dressing. This allowed the dressing to be cut down to about 2.5 cm size portions for smaller dressing needs while still providing at least one weld in the dressing portion [0197].

f. These teachings provide for outermost surfaces coated with indicator blue layers with silver layers below the indicator layers with subsequent outer dressing layers with an interior absorbent core. While the applied reference does not teach coating both the interior and exterior sides of the outer dressing layers with silver it would have been obvious to one of ordinary skill in the art to have coated the interior facing sides of the outer dressing layers as well as the exterior facing sides with antimicrobial silver. The skilled artisan would have been motivated by the desire to impart more antimicrobial properties to the article and the fact that the middle absorbent layer is designed to hold

sufficient moisture next to the skin in order to activate the antimicrobial metal coating, that is to cause release of ions, molecules, atoms or clusters of the antimicrobial metal in order to cause an antimicrobial and anti-inflammatory effect. The most efficient way for this to occur is for the antimicrobial metal layers to be located on the interior of the outer dressing layers. Further support for this position is provided by the fact that the applied reference teaches the use of a silver coating on multiple dressing layers, which allows for additional silver to be administered. Examiner has interpreted the limitation of "exterior surfaces of the composite" to mean the surface that is exposed to visual inspection. In this case the blue indicator layer is located on the exterior surfaces of the composite.

Claim 170 is rejected as the arrangement of the silver and Al layers may be interchanged.

Claim 207 is rejected as the interior silver coating may be co-deposited with Al [0132].

g. Although Burrell et al. do not explicitly teach the claimed feature of a specified liquid-absorbing capacity, it is reasonable to presume that said property is inherent to Burrell et al. Support for said presumption is found in the use of like materials (i.e. the second layer, i.e. the absorbent layer, is made of polyethylene which anticipates claims 131 and 132). The burden is upon Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of the specified liquid-absorbing capacity would obviously have been present one the Burrell et al. product is provided.

h. Although Burrell et al. do not explicitly teach the feature of the instantly claimed 24-hour release of the antimicrobial metal rate or its silver content, it is reasonable to presume that said properties are inherent to Burrell et al. Support for said presumption is found in the use of like materials (i.e. a two layer absorbent article of comprising liquid

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permeable layer with an antimicrobial metal in elemental form). The burden is upon Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties of the antimicrobial release rate and silver content would obviously have been present one the Burrell et al. product is provided.

3. Claims 113-118, 124, 133-136, 142-146, 152-162, 165, 166, 168, 169, 171-173, 186, 187, 190, 194, 195, 200-205, 208 and 210 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 2003/0054046) as applied to claims 105, 112, 125, 128, 180 and 193 above, and further in view of Kirkwood et al. (US 2004/0241214). Burrell et al. is silent as to the physical limitations to the outer layers of the dressing.

a. Kirkwood et al. teach a wound dressing comprising a liquid-permeable, apertured wound-facing surface with a plurality of microsphere particles comprising silver located behind the wound-facing surface (Abstract and [0052]). The Examiner equates the applied apertured fabric to Applicant's mesh structure. An absorbent layer may be located behind the layer of silver particles [0054-0056]. The apertured sheet may be made of polyethylene [0015]. The apertures may have diameters between 113 μ m and 3.57mm and may be round, oval, or regular polygonal [0037, calculation performed by Examiner]. The apertures make up about 0.1% to 50% of the sheet area [0016].

b. The absorbent layer or second layer is to be from 0.2mm to 10mm thick and have a basis weight that ranges from 50-500 g/m² [0056]. The absorbent layer may comprise a nonwoven fibrous web of viscose staple fibers and superabsorbent, or may be polyurethane foam [0056]. Both examples of absorbent layers are liquid-permeable and absorbing.

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c. Since Kirkwood et al. and Burrell et al. are from the same field of endeavor (i.e. antimicrobial dressings), the purpose disclosed by Kirkwood et al. would have been recognized in the pertinent art of Burrell et al.

d. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the invention of Burrell et al. with the structural limitations of the dressing layers of Kirkwood et al. The skilled artisan would have been motivated by the desire to create an article that successfully disperses the antimicrobial material to the wound, while maintaining the article's structural integrity.

e. The applied publications are silent as to the thickness of the first, wound-facing fabric. However, Kirkwood et al. do teach a thickness for the second layer of 0.2 to 10mm and Burrell et al. teach the use of the same fabrics for both layers. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the first, wound-facing layer with a thickness of from about 0.2 to about 10mm.

f. Provided both layers of Burrell et al. were made of the instantly claimed materials, thicknesses, and basis weights the article would comprise a two-layered apertured polyethylene sheet, with an overall thickness of 0.4mm to 20mm and basis weight of 100-1000 g/m².

g. Although Burrell et al. do not explicitly teach the claimed peeling strength or maximum tensile strength, it is reasonable to presume that said properties are inherent to Burrell et al. Support for said presumption is found in the use of like materials (i.e. polyethylene absorbent article) and more importantly a common utility (i.e. adhesive

wound dressing). The burden is upon Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties of peeling strength and maximum tensile strength would obviously have been present one the Burrell et al. product is provided.

h. Although the applied references do not explicitly teach the feature of the instantly claimed 24-hour release of the antimicrobial metal rate, it is reasonable to presume that said property is inherent to combined invention because the instantly claimed antimicrobial metal and its form are in common with one another. Support for said presumption is found in the use of like materials (i.e. a two layer absorbent article of comprising liquid permeable layer with an antimicrobial metal in elemental form). The burden is upon Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of the antimicrobial release rate would obviously have been present one the combined product is provided. Reliance upon inherency is not improper even though rejection is based on Section 103 instead of Section 102. *In re Skoner, et al.* (CCPA) 186 USPQ 80.

i. The applied references are silent as to the amount of silver to be used in the applied anti-microbial metal wound dressing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the wound dressing of Burrell et al. with the instantly claimed silver metal levels, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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4. Claims 137, 138 and 196 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 2003/0054046) in view of Kirkwood et al. (US 2004/0241214) as applied to claims 136 and 195 respectively, further in view of Burton (US 6,903,243). The applied references are silent as to the use of a superabsorber comprising a polymer having recurring units derived from acrylic acid and derivatives thereof.

a. Burton teaches a multilayer absorbent wound dressing comprising an absorbent layer of 0-30 parts by weight of an acrylic or methacrylic acid ester (col. 4, lines 55-62).

The applied invention may also include antibacterial silver (col. 12, lines 31-34).

b. Since both Burrell et al. and Burton are from the same field of endeavor, (i.e. multilayer absorbent wound dressings comprising silver), the purpose disclosed by Burton would have been recognized in the pertinent art of Kirkwood et al.

c. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the wound dressing of Burrell et al. with the superabsorbent and superabsorbent percentage of Burton with the motivation of creating a highly effective absorbent article.

Double Patenting

5. Claims 105-187, 189, 190, and 192-210 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 and claims 1-36 of copending Application Nos. 11/255,956 and 11/255,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because all three applications are directed to antimicrobial wound dressing composite comprising two layers with a silver coating between said layers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

6. Applicant's arguments with respect to claims 105-187, 189, 190, and 192-210 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Matzek whose telephone number is (571) 272-2423. The examiner can normally be reached on 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mdm *MDM*



Norca L. Torres-Velazquez
Primary Examiner
Art Unit 1771

10/27/06